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Cognitive training as a facilitated self-help relapse prevention for depression

Submission date
31/03/2010

Recruitment status
No longer recruiting

Registration date
31/03/2010

Overall study status
Completed

Last Edited
14/06/2016

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Depression is an extremely common mental health problem that is most commonly treated with antidepressant drugs. Even though antidepressant drugs help many people with depression get well, the rates of people getting depressed again are high. Patients often report that they would like alternative treatment to help them recover from depression in the long-term, and would prefer psychological therapies. We need to develop therapies that help to treat and prevent depression and that are easily accessible in the NHS. The use of facilitated self-help interventions, in which people practise strategies to reduce depression on their own, with some guidance from therapists, have been suggested as one way to make sure that therapy is easily accessible to as many people as possible. This research prepared for a large scale study looking at how well different forms of facilitated self-help can prevent future depression.
This study investigated whether facilitated self-help can help reduce the risk of future episodes of depression in people with a history of depression. The aim was to investigate the feasibility of facilitated guided self-help as a means to reduce the future risk for depression, to determine whether this approach is able to recruit sufficient participants, whether the treatments are acceptable to patients, and to obtain an initial estimate of their effects.

Who can participate?
Participants were male or female and aged over 18 years old. Because this was a study of preventing future relapse in depression, the study recruited individuals at increased risk for depression on the basis of two or more previous episodes of major depression with the most recent episode occurring within the last 5 years, and no current episode of depression.

What does the study involve?
Participants were randomly allocated to cognitive training self-help in addition to standard treatment or to relaxation self-help in addition to standard treatment. The treatment part of the study lasted approximately 8 weeks. The total study lasted up to 9 months and involved an initial assessment of depression, and then further assessments post-treatment, and follow-up assessments 3 months and 6 months later. Facilitated self-help is a self-guided therapy that involves daily practise at exercises that are designed to reduce depression. These exercises work by changing the way that people respond to their feelings and their difficulties through repeated practise at trying new ways of responding to and thinking about emotional events.

Both facilitated self-help interventions consisted of: (a) An initial meeting lasting x 1.5 hours, during which the researcher explained the rationale for why the self-help training is helpful and then practised the facilitated self-help exercises with the participant, (b) The participant practising the self-help exercises training with audiotape/CD and/or computer-based programmes for up to 30 minutes every day for 6-8 weeks. The facilitated self-help exercises involved the use of mental imagery, relaxation, memory exercises and/or attention exercises, for example imagining emotional events in different ways in order to practise different ways of responding to emotional events. The self-help package also included written information about depression and about how to cope with depression. The actual time spent on the exercises each day was up to each individual, although we recommended 30 minutes every day for 6-8 weeks. The self-help was facilitated by up to 3 telephone therapy sessions.
We compared two versions of facilitated self-help with different mental exercises. One form is called cognitive training and involves learning mental exercises to break out of unhelpful patterns of thinking. The other form is called relaxation and involves learning exercises to reduce feelings of stress and tension. Both of these forms of self-help were expected to reduce the risk of future depression.
Half of the participants received the cognitive training facilitated self-help and half of the participants received the relaxation facilitated self-help. The facilitated self-help was received in addition to whatever treatment was being provided by the participants general practitioner, including antidepressant medication.

What are the possible benefits and risks of participating?
We hoped that the facilitated self-help interventions would help participants by reducing their vulnerability to future episodes of depression. Self-help treatments are recommended as helpful treatments for recurrent depression. Participants also gained formal assessment of their symptoms and close monitoring of their progress over 6 months, which some people find to be of benefit.
Moreover, the information we got from this study may help us to treat future patients with depression better. Because this was exclusively a psychological treatment, there were no physical or medical side effects of the treatments. This research involved participants giving their time to complete the questionnaires and discuss with the researchers how they were doing every three months. Some of the questions were personal and sometimes people can find it upsetting to discuss these issues.

Where is the study run from?
The study was run from the Mood Disorders Centre, Department of Psychology, University of Exeter, which is the lead centre for the project. Recruitment for the study occurred across a number of GP surgeries within Exeter, East and North Devon.

When is the study starting and how long is it expected to run for?
March 2008 to March 2010

Who is funding the study?
The Wellcome Trust (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Protocol serial number
4579; 080099

Study information

Scientific Title
Cognitive training as a facilitated self-help relapse prevention for depression: a randomised interventional single-centre prevention trial

Study objectives
1. Can concreteness cognitive training facilitated self-help produce robust and stable shifts in thinking style in individuals with a history of major depression, relative to an active intervention controlling for non-specific factors (relaxation)?
2. Can cognitive training facilitated self-help in addition to treatment-as-usual significantly reduce rumination and vulnerability to depression in depressed patients relative to an active intervention controlling for non-specific factors (relaxation)?
3. Is cognitive training feasible and acceptable as a potential self-help intervention?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Devon and Torbay REC, 18/03/2008, ref: 08/H0202/22

Study design
Randomised interventional single-centre prevention trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Topic: Mental Health Research Network, Primary Care Research Network for England; Subtopic: Depression, Not Assigned; Disease: Depression, All Diseases

Interventions
1. Cognitive training self-help in addition to treatment-as-usual
2. Relaxation training self-help in addition to treatment-as-usual. The cognitive training facilitated self-help intervention will consist of an initial meeting lasting approx 1.5 hours (subject to modification as the project progresses), during which the researcher will explain the rationale for why cognitive training is helpful and then practice relaxation or the cognitive training paradigm.

Follow Up Length: 6 month(s)
Study Entry: Single Randomisation only

Intervention Type
Other

Phase
Phase III

Primary outcome(s)
Hamilton Rating Scale for Depression - 17 item version (HRS-D), measured at pre-treatment baseline, 2 months post-baseline(post-intervention), at 3 month follow-up (i.e., 5 months post-baseline) and at 6 month follow-up (i.e., 8 months post-baseline)

Key secondary outcome(s))
Depressive symptoms: the Beck Depression Inventory (BDI-II), measured at pre-treatment baseline, 2 months post-baseline(post-intervention), at 3 month follow-up (i.e., 5 months post-baseline) and at 6 month follow-up (i.e., 8 months post-baseline

Completion date
30/08/2009

Eligibility

Key inclusion criteria
1. History of at least two previous episodes of major depression, not currently depressed
2. Aged 18 years or over, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Current psychotherapy
2. Psychosis
3. Current substance/alcohol use

Date of first enrolment
28/03/2008

Date of final enrolment
30/08/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Mood Disorders Centre
Exeter
United Kingdom
EX4 4QG

Sponsor information

Organisation
University of Exeter (UK)

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type

Charity

Funder Name
Wellcome Trust (grant ref: 080099)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes